

**F A C S I M I L E C O V E R S H E E T****Licata & Tyrrell P.C.**

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March 15, 2005

**TO:** Mrs. Pinkney  
US Patent and Trademark Office

**GROUP:** 1632

**FAX NUMBER:** 703-308-6642

**ATTORNEY DOCKET NO.:** DEX-0054

**SERIAL NO.:** 09/426,548

**FILED:** October 22, 1999

**NUMBER OF PAGES:** 8

**MESSAGE:**

Dear Mrs. Pinkney:

Attached please find a copy of the Supplemental Information Disclosure Statement as filed on February 29, 2000.

Thank you, Mariana for: Kathleen A. Tyrrell, Registration No. 38,350

**URGENT! PLEASE DELIVER IMMEDIATELY UPON RECEIPT. THANK YOU!**

\* \* \* \* \*

If you have any questions, or did not receive the proper number of pages, or had trouble during transmission, please call 856-810-1515.

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0054  
Inventors: ROBBINS ET AL.  
Serial No.: 09/426,548  
Filing Date: OCTOBER 22, 1999  
Examiner: NOT YET ASSIGNED  
Group Art Unit: 1632  
Title: NOVEL MUTATIONS IN HUMAN MLH1 AND HUMAN  
MSH2 GENES USEFUL IN DIAGNOSING  
COLORECTAL CANCER

I, Jane Massey Licata, Registration No. 32,257, certify that this correspondence is being depositing with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On this date: February 29, 2000

Jane Massey Licata  
Jane Massey Licata, Registration No. 32,257

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into

the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

( ) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

( ) Certification in Accordance with §1.97(e) is set forth below; or

( ) The fee of \$240.00 as set forth in §1.17(p) is attached.

( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(i)(1).

(XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously

submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 12-1086. This form is submitted in duplicate.

( ) The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,

*Jane Massey Licata*

Jane Massey Licata  
Registration No. 32,257

Date: February 29, 2000

Law Offices of  
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66 E. Main Street  
Marlton, New Jersey 08053

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## Form PTO-1449 Modified

List of Patents and Publications  
Cited by Applicant  
(Use several sheets if necessary)

U.S. Department of Commerce

Docket No.  
DEX-0054

Serial No.  
09/426,548

Applicant  
ROBBINS ET AL.

Filing Date  
OCTOBER 22, 1999

Group  
1632

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AA	Bronner et al., "Mutation in the DNA mismatch repair gene homologue hMLH 1 is associated with hereditary non-polyposis colon cancer", 1994 Nature 368; 258-261
AB	Burke et al., "Recommendations for Follow-up Care of Individuals With an Inherited Predisposition to Cancer", 1997 J. Am. Med. Assoc. 277(11) 915-919
AC	Dunlop et al., "Screening for people with a family history of colorectal cancer", 1997 314; 1779-1790
AD	Dutton et al., "Simultaneous Detection of Multiple Single-Base Alleles at a Polymorphic Site", 1999 Biotechniques 11; 700-702
AE	Fishel et al., "The Human Mutator Gene Homolog MSH2 and Its Association with Hereditary Nonpolyposis Colon Cancer", 1993 Cell 75; 1027-1038
AF	Frohman et al., "Cut, Paste and Save: New Approaches to Altering Specific Genes in Mice", 1989 Cell 56; 145-147
AG	Giardiello et al., "The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis", 1997 New Engl. J. Med. 336; 823-827
AH	Han et al., "Genomic structure of human mismatch repair gene, hMLH1, and its mutation analysis in patients with hereditary non-polyposis colorectal cancer (HNPCC) 1995 Human Mol. Genet. 4(2) 237-242
AI	Kohler et al., "Continuous cultures of fused cells secreting antibody of predefined specificity", 1975 Nature 256; 495-497
EXAMINER	
DATE CONSIDERED	

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<b>Form PTO-1449 Modified</b> List of Patents and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce		Docket No. <b>DEX-0054</b>	Serial No. <b>09/426,548</b>
		Applicant <b>ROBBINS ET AL.</b>	
		Filing Date <b>OCTOBER 22, 1999</b>	Group <b>1632</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	AJ	Kolodner et al., "Structure of the Human MLH1 Locus and Analysis of a Large Hereditary Nonpolyposis Colorectal Carcinoma Kindred for mlh1 Mutations <sup>1</sup> ", 1995 <i>Cancer Research</i> 55; 242-248	
	AK	Kolodner et al., "Structure of the Human MSH2 Locus and Analysis of Two Muir-Torre Kindreds for msh2 Mutations", 1994 <i>Genomics</i> 24; 516-526	
	AL	Leach et al., "Mutations of a mutS Homolog in Hereditary Nonpolyposis Colorectal Cancer", 1993 <i>Cell</i> 75;1215-1225	
	AM	Liu et al., "hMSH2 Mutations in Hereditary Nonpolyposis Colorectal Cancer Kindreds <sup>1</sup> " 1994 <i>Cancer Research</i> 54; 4590-4594	
	AN	Liu et al., "Analysis of mismatch repair genes in hereditary non-polyposis colorectal cancer patients", 1996 <i>Nature Medicine</i> 2; 169-174	
	AO	Liu et al., "Genetic instability occurs in the majority of young patients with colorectal cancer", 1995 <i>Nature Medicine</i> 1; 348-352	
	AP	Lynch et al., "Genetics, Natural History, Tumor Spectrum, and Pathology of Hereditary Nonpolyposis Colorectal Cancer: An Updated Review", 1993 <i>Gastroenterology</i> 104; 1535-1549	
	AQ	Mary et al., "Mutational analysis of the hMSH2 gene reveals a three base pair deletion in a family predisposed to colorectal cancer development", 1994 <i>Human Molecular Genetics</i> 3(11) 2067-2069	
	AR	Newton et al., "Analysis of any point mutation in DNA. The amplification refractory mutation system (ARMS)", 1989 <i>Nucleic Acids Research</i> 17; 2503-2516	
EXAMINER		DATE CONSIDERED	

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## Form PTO-1449 Modified

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Cited by Applicant  
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ROBBINS ET AL.

Filing Date

OCTOBER 22, 1999

Group

1632

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AS

Nicolaides et al., "Mutations of two PMS homologues in hereditary nonpolyposis colon cancer", 1994 *Nature* 371; 75-80

AT

Nystrom-Lahti et al., "Founding mutations and Alu-mediated recombination in hereditary colon cancer", 1995 *Nature Medicine* 1(11); 1203-1206

AU

Okayama et al., "Rapid, nonradioactive detection of mutations in the human genome by allele-specific amplification", 1989 *J. Lab. Clin. Med.* 1214; 105-113

AV

Papadopoulos et al., "Mutation of a mutL Homolog in Hereditary Colon Cancer", 1994 *Science* 263; 1625-1629

AW

Parker et al., "AmpliTag DNA Polymerase, FS Dye-Terminator Sequencing: Analysis of Peak Height Patterns", 1996 *Biotechniques* 21; 694-699

AX

Sarkar et al., "Characterization of Polymerase Chain Reaction Amplification of Specific Alleles", 1990 *Anal. Biochem.* 186; 64-68

AY

Sommer et al., "A Novel Method for Detecting Point Mutations for Polymorphisms and Its Application to Population Screening for Carriers of Phenylketonuria", 1989 *Mayo Clin. Proc.* 64; 1361-1372

AZ

Tomlinson et al., "Germline HNPCC gene variants have little influence on the risk for sporadic colorectal cancer", 1997 *J. Med. Genet.* 34; 39-42

BA

Vasen et al., "The International Collaborative Group on Hereditary Non-Polyposis Colorectal Cancer (ICG-HNPCC), 1991 34; 424-425

EXAMINER

DATE CONSIDERED

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1632

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BB

Wijnen et al., "Seven New Mutations in hMSH2, an HNPCC  
Gene, Identified by Denaturing Gradient-Gel  
Electrophoresis", 1995 *Am. J. Hum. Genet.* 56; 1060-1066

BC

Wu et al., "Allele-specific enzymatic amplification of  
 $\beta$ -globin genomic DNA for diagnosis of sickle cell  
anemia", 1989 *Proc. Natl. Acad. Sci. USA* 86; 2757-2760

EXAMINER

DATE CONSIDERED

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